K082128

510(k) Summary

SUBMITTER: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02780

NOV 14 2008

CONTACT PERSON: Hande Tufan

DATE PREPARED: June 1, 2008

CLASSIFICATION NAME: Intervertebral Fusion Device with Bone Graft – 87MAX – 888.3080 – Class II

PROPRIETARY NAME: Lateral Cage System

PREDICATE DEVICES: LUMBAR I/F CAGE System (P960025)
NuVasive CoRoent System (K071795)

DEVICE DESCRIPTION: The Lateral Cage System consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft materials.

The Lateral Cage System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

INTENDED USE: The Lateral Cage System is indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. The Lateral Cage System is intended for use with DePuy Spine supplemental fixation.

MATERIALS: Manufactured from Carbon Fiber Reinforced Polymer.

PERFORMANCE DATA: Performance data were submitted to characterize the Lateral Cage System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Spine
% Ms. Hande Tufanyazici
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham Massachusetts 02767

NOV 14 2008

Re: K082128
Trade/Device Name: Lateral Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: November 07, 2008
Received: November 12, 2008

Dear Ms. Tufanyazici:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known): K082128

Device Name: Lateral Cage System

Indications For Use:

The Lateral Cage System is indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach.

The Lateral Cage System is intended for use with DePuy Spine supplemental fixation.

Prescription Use: _____X_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082128